525 Rec'd PCT/PTO 22 NOV 2000

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FORM PTO-1390 (REV 12-29-99) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER LUD-PT002 (PA1083US)
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 09/701104 Not Yet Known
INTERNATIONAL APPLICATION NO. PCT/EP99/03618	INTERNATIONAL FILING DATE 26 May 1999	PRIORITY DATE CLAIMED 27 May 1998
TITLE OF INVENTION COMPOSITE OF POLYMER OR CERAMIC MATERIALS AND COMPONENT MADE OF SUCH A COMPOSITE		
APPLICANT(S) FOR DO/EO/US Magerl et al.		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [X] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [X] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [X] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [X] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [X] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A FIRST preliminary amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [X] Other items or information:
    Examination is to be based on the translation of the Annexes to the International Preliminary Examination Report, which includes pages 1-10 of the specification and pages 11-13 of the claims.

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U.S. APPLICATION NO (if known, see 37 CFR 1 5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
Not Yet Known 09/701104	PCT/EP99/03618	LUD-PT002 (PA1083US)

17. [x] The following fees are submitted:

	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO .... **$1,000.00** International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO....... **$860.00** International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO .... **$710.00** International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) .... **$690.00** International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 860	
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	15 - 20 =	0	X **$18.00**	$	
Independent claims	1 - 3 =	0	X **$80.00**	$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$260.00**	$	

TOTAL OF ABOVE CALCULATIONS =	$	
Reduction of 1/2 for filing by small entity, if applicable. A Small Entity Statement must also by filed (Note 37 CFR 1.9, 1.27, 1.28).	$	
SUBTOTAL =	$	
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +	$	
TOTAL NATIONAL FEE =	$ 860	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +	$	
TOTAL FEES ENCLOSED =	$ 860	
	Amount to be refunded:	$
	charged:	$

a. [x] A check in the amount of $860 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. ________ in the amount of $________ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [x] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 22-0493. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Volpe and Koenig, P.C.
Suite 400, One Penn Center
1617 John F. Kennedy Boulevard
Philadelphia, PA 19103

SIGNATURE

Randolph J. Huis, Esquire
NAME

34,626
REGISTRATION NUMBER

Express Mail Label No. EL736679975US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the **PATENT APPLICATION** of:	
	Magerl et al.
PCT Appln. No.:	PCT/EP99/03618
U.S. Appln. No.:	Not Yet Known
Filed:	Not Yet Known
For:	COMPOSITE OF POLYMER OR CERAMIC MATERIALS AND COMPONENT MADE OF SUCH A COMPOSITE
Group:	Not Yet Known
Examiner:	Not Yet Known

Our File: LUD-PT002 (PA 1082US)

Date: November 22, 2000

PRELIMINARY AMENDMENT

Box PCT
Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to calculation of the filing fee and examination, please amend the present application as provided in the translation of the Annexes to the International Preliminary Examination Report as noted below.

IN THE SPECIFICATION

On page 1, line 3, replace "DESCRIPTION" with --BACKGROUND--.

On page 2, after the fourth paragraph, please insert --SUMMARY--.

On page 7, after line 3, insert --BRIEF DESCRIPTION OF THE DRAWINGS--.

On page 7, after line 7, insert --DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS--.

IN THE CLAIMS

On page 11, delete all of the information above the heading "CLAIMS".

In claim 3, line 1, delete "or 2".

In claim 4, line 1, delete "one of claims 1 to 3" and insert --claim 1--.

In claim 5, line 1, delete "one of claims 1 to 4" and insert --claim 1--.

In claim 6, line 1, delete "claims 1 to 5" and insert --claim 1--.

In claim 7, line 1, delete "claims 1 to 6" and insert --claim 1--.

In claim 8, line 1, delete "claims 1 to 7" and insert --claim 1--.

In claim 9, line 1, delete "claims 1 to 8" and insert --claim 1--.

In claim 11, line 1, delete "and 10".

In claim 12, line 1, delete "claims 9 to 11" and insert --claim 9--.

In claim 13, lines 1-2, delete "claims 9 to 12" and insert --claim 9--.

In claim 14, lines 1-2, delete "one of claims 9 to 13" and insert --claim 9--.

In claim 15, line 2, delete "one of claims 9 to 14" and insert --claim 9--.

REMARKS

By the foregoing amendment, applicants have amended the specification, as provided by the translation of the Annexes to the International Preliminary Examination Report, to provide the headings required for U.S. practice. The claims have also been amended in order to eliminate the multiple dependencies in order to avoid excess claim fees.

Prompt examination of this application is respectfully requested.

Respectfully submitted,

Magerl et al.

By [signature]
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(215) 568-6400

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RJH/tc

09/701104

529 Rec'd PCT/PTC 22 NOV 2000

Express Mail Label No. EL736679975US
Attny. Docket No. LUD-PT002 (PA1083US)

Translation of the Annexes to The International Preliminary Examination Report

Subject: COMPOSITE OF POLYMER OR CERAMIC MATERIALS AND COMPONENT MADE OF SUCH A COMPOSITE

Description

The invention relates to a composite of polymer or ceramic material with a content of integrated reinforcing elements in the form of fibers or fibrous parts, for the manufacture of components exposed to tensile, bending, shear, compressive and/or torsional stress for use in implants, e.g., osteosynthesis plates, endoprostheses, screw coupling elements, in surgical instruments, etc., and a component made of such a composite.

Composites having the most varied of composition are achieving a steadily growing acceptance as implants precisely in the area of surgery. Advantageous knowledge can be gained during manufacture already, particularly since shrinking during polymerization is being improved relative to pure plastics. Mechanical strength values, e.g., compressive strength, rigidity and modulus of elasticity. In addition, the thermal expansion coefficient can be reduced in comparison to pure plastic.

For example, EP-A-0 551 574 shows a multiple-layer composite for achieving high strength made out of thermoplastics, e.g., polyaryl ketones, which contains braided metal fibers, so that the implant can be easily detected with X-rays.

EP-A-0 572 751 describes an endoprosthesis comprised of a compact, thermoplastic composite made out of thermoplastics, e.g., polyarylether ketone and continuous fibers (with areas of varying fiber orientation), wherein the endoprosthesis contains a metal lattice.

GB-A-2 203 342 describes an implant, e.g., made out of woven polyester, which contains a metal (Au, Pt, Ti, Pd) as a wire or lattice to enable detection.

One often perceived disadvantage to such components fabricated out of composites is that the used implants, e.g., osteosynthesis plates, bone screws, etc., cannot be detected during X-ray examination. It is precisely for this reason that implants consisting of metal or metal parts are often still used.

The use of an X-ray opaque material is already known in dental technology, which is intended to make a corresponding dental filling material visible during X-rays, such a material cannot be used for implants that must exhibit a corresponding strength and have a correspondingly high percentage of strength-increasing fibers. If an X-ray opaque filler were then to be additionally introduced into the matrix material, there would no longer be any guarantee that the used fibers are still correctly embedded. This would substantially diminish the strength of such a component. It is simply not possible to incorporate other fillers into a fiber-reinforced composite in addition to the fibers.

Therefore, the object of this invention is to provide a composite of the kind mentioned at the outset that enables the attainment of identical or even in part improved strength characteristics for the components made out of the composite, while additionally permitting a good visibility during X-ray diagnostics.

According to the invention, the object is achieved by having the polymer or ceramic material incorporate at least a small

percentage of the content of reinforcing elements, e.g., in the form of fibers or fibrous parts made out of a material with a higher X-ray absorption.

Despite the existence of additional reinforcing elements with a higher X-ray absorption, or also the complete or partial replacement with already present reinforcing elements, this measure yields a strength for the composite equal to or even better than the previous configuration. The reinforcing elements with a higher X-ray absorption are also fibers or fibrous parts, which, in addition to now enabling X-ray diagnostics, yield a corresponding strength in the implants. These fibers or fibrous parts consisting of a material with a higher X-ray absorption enable X-ray visibility, as a rule without disrupting other imaging procedures, like CT, NMR, MRI, etc. The fibers or fibrous parts are also non-disruptive during radiation treatment, since they produce no relevant shadowing effect. However, the significant advantage lies precisely in the fact that the fibers or fibrous parts with a higher X-ray absorption yield an increased strength in the implants made out of them. By contrast, other fillers or X-ray opaque mixtures, e.g., particulate metal oxides, diminish the strength.

It is additionally proposed for the composite that it consist of a polymer or ceramic material with a high fiber percentage, primarily using continuous, long or short fibers, wherein at least a small percentage of fibers or fibrous parts consist of a material with a high X-ray absorption. Despite a very high percentage of continuous fibers, the volume percentage of residual material can be retained, and the existing strength characteristics can be retained or even enhanced through the sole replacement of otherwise present fibers with fibers consisting of a material with a high X-ray absorption.

In one advantageous design, the composite is prefabricated as a rod material consisting of thermoplastic materials with carbon

fibers and fibers made out of a material with a high X-ray absorption, and can be or has been molded into a shape required for the final component in a thermoforming process. Despite the special composition with fibers comprised of varying materials, good thermoformability can be retained, thereby enabling an optimal production of even relatively complicated components even with a composite improved in this manner.

In one embodiment, it is proposed that the composite consist of carbon fiber-reinforced PAEK (poly-aryl-ether-ketone) and a percentage of fibers made out of a material with a high X-ray absorption. This makes it a material with a special compatibility, high strength and the visibility necessary for X-ray diagnostics.

Optimal strength levels can be achieved by designing the carbon fibers and fibers made out of a material with a higher X-ray absorption as continuous fibers and/or fibers with a length exceeding 3 mm.

To enable a transfer of force between the fibers and the other material of the composite, i.e., to also ensure an optimal strength at a high volume density of fibers, it is provided that the used fibers be enveloped on the surface by the matrix material both in the preform and the finished component.

Steel fibers could in themselves also be used as an X-ray opaque material, but would then end up giving rise to other problems for implants, e.g., artifacts in an MRI, NMR, etc. Therefore, the fibers or fibrous parts comprised of a material with a high X-ray absorption are advantageously made out of a nonmagnetic material.

Therefore, it is viewed as particularly advantageous for the fibers or fibrous parts with high X-ray absorption to consist of tantalum, tungsten, gold, platinum, etc., meaning of a metal or metal oxides with a high attenuation coefficient.

The component according to the invention made out of such a composite is characterized by the fact that, a predictable progression and predictable quantity and orientation of reinforcing elements in the form of fibers or fibrous parts made out of a material with a high X-ray absorption, are provided, tailored to the shape and application of the component. Therefore, it is possible to graduate the visibility of the component, i.e., of an implant. Depending on the segments of an implant where a stronger, weaker or even no X-ray visibility is desired, it is possible to control the application and used quantity of fibers made out of X-ray opaque materials. Hence, the ability to concentrate or accumulate these fibers is of particular importance.

In this connection, it is then also possible that areas of differing fiber orientation or fiber progression are provided relative to the longitudinally or transverse oriented alignment of the component. This can also be a positive influence on an even more informative X-ray diagnostics.

In one special design variant, the ratio of carbon fibers to fibers or fibrous parts made out of a material with a high X-ray absorption can be or is variable at a total fiber percentage of 50 %v/v, for example, depending on the application requirement. Therefore, a component with the same or even better strength values is achieved, even though the overall volume percentage of the fibers is not increased.

So that components can be precisely adjusted to the conditions for use, it is proposed that the total fiber percentage in the composite remains constant over their length or width, but this changes the ratio of carbon fibers to fibers or fibrous parts made out of a material with a high X-ray absorption, depending on the application requirement. Therefore, the visibility can be

deliberately controlled for an optimal X-ray diagnostics, without impairing the strength values.

However, it is also possible within the framework of the invention to vary the stiffness of the connecting element by varying the orientation of used fibers from the force application point toward the free end. This can be desired in a connecting element, e.g., a screw, if various areas are to exhibit a greater flexibility than other sections during use. This also enables a precise adjustment to the conditions existing in the area of a bone.

In this case, it is not only possible to smoothly adjust the strength of such a component. It is also proposed that the stiffness of the component be incrementally or continuously tapered by varying the orientation of the fibers viewed from the force application point to the free end.

In a special design variant of a component in the form of a strip or plate assembly part, e.g., an osteosynthesis plate, it is proposed that a concentration of fibers be present in the area of one or more recesses or holes in the component, wherein the percentage of fibers or fibrous parts made out of a material with a high X-ray absorption is reduced in these areas, if necessary. Therefore, it can be ensured that there will also not be a strong concentration of fibers made out of a material with a high X-ray absorption in an area with a highly concentrated arrangement of fibers. Under certain conditions, this would not be conducive for a targeted X-ray diagnostics. By contrast, this can be achieved by keeping the content of fibers made out of a material with a high X-ray absorption constant as desired over the entire length and/or width of a component, meaning also in the area of recesses or holes.

Therefore, the application of the composite according to the invention and its use in manufacturing components according to

the invention has created numerous new ways of performing an optimal X-ray diagnostics when using implants made out of such materials.

Additional details will be explained in even greater detail in the description below. Shown on:

Fig. 1 is a component in the form of a bone screw;
Fig. 2 is a component in the form of an osteosynthesis plate.

On the one hand, this invention involves a composite consisting of polymer or ceramic material with a content of integrated reinforcing elements in the form of fibers or fibrous parts, for the manufacture of components exposed to tensile, bending, shear, compressive and/or torsional stress for use in implants, e.g., osteosynthesis plates, endoprostheses, screw coupling elements, in surgical instruments, as already enumerated above. In this case, it is regarded as essential to provide at least a small percentage of the content of fibers or fibrous parts made out of a material whose X-ray absorption is higher than the that of the remaining fibers or fibrous parts in the polymer or ceramic material.

In one embodiment, the composite consists of a polymer or ceramic material with a fiber percentage of more than 50 %v/v, with primarily continuous fibers being used. At least a small share of fibers or fibrous parts consists of a material with a higher X-ray absorption than that of the remaining fibers or fibrous parts. In this case, prefabrication can take place as a profiled rod material comprised of thermoplastics with carbon fibers and fibers made out of a material with a high X-ray absorption. Final production of the component out of the composite then takes place in a thermoforming process. Therefore, the material is pressed into a shape required for the final component. In one special variant, the composite consists of carbon fiber-reinforced PAEK (poly-acryl-ether-ketones) and a percentage of fibers made out of

a material with a higher X-ray absorption. Even though the fibers consist of a material with a higher X-ray absorption, optimal processability is retained, and no additional tool wear comes about. Not only does this enable processing via pressing in a thermoforming procedure, fabrication in an injection molding process is also possible.

Use of the composite also ensures the biocompatibility of the finished component.

The fibers or fibrous parts made out of a material with a higher X-ray absorption in the composite are formed out of a nonmagnetic material. Particularly suited here are fibers or fibrous parts with a high X-ray absorption comprised of tantalum, tungsten, gold, platinum, etc., meaning a metal with a high attenuation coefficient. Within the framework of the invention, it would also be conceivable to use ceramic fibers made of oxides of elements with a high X-ray absorption, for example. Fibrous parts can also include long or short fibers, or additional other fillers to be used without lowering the strength. With respect to the existing reinforcing elements, it is possible to use the same or similar reinforcing elements in the form of fibers or fibrous parts. „Similar„ here denotes the same or similar dimension and/nor same or similar mechanical properties.

The essence of the invention can only be illustrated on a small scale in the depictions shown on the drawing. The following explanations therefore become necessary. The component 1 in the form of a screw shown on Fig. 1 essentially consists of a head 2, force application point 3 for introducing the force from a lathe tool, and a shank 5 furnished with a thread 4. The key factor in such a component 1 is the special progression and arrangement of continuous fibers 6. Selecting a composite of thermoplastics with carbon fibers makes it possible to fabricate a light, X-ray transparent and biocompatible connecting element. However, in order to make this connecting element precisely during X-ray

diagnostics, the measures described in the invention are necessary, namely having a portion of the fibers 6 consist of a material with a high X-ray absorption.

The measures according to the invention can be implemented for practically all implants, meaning also for rail or plate-shaped components 18. Fig. 2 diagrammatically depicts such a component 18 in the form of an osteosynthesis plate. Through holes 14, indentations, blind holes, etc. are provided in such components, which then are surrounded in a special manner by the fibers. Without taking any additional measures aimed at deliberately controlling the quantity and alignment of fibers 6, a denser arrangement of fibers 6 arises in the normally weakened zones A, so that these zones A have the same strength or stiffness as the other areas B of such a component. During fabrication in a thermoforming process, in particular via push-pull extrusion, the progression and alignment of the fibers 6 can still be additionally controlled, and hence influenced.

All used fibers 6, or at least a large percentage of them, i.e., the carbon fibers and fibers made out of a material with a higher X-ray absorption, are advantageously designed as continuous fibers or fibers with a length exceeding 3 mm. In this case, care is taken for strength reasons to envelop the surface of the incorporated fibers by the matrix material in both the perform and finished component.

In the component 1 or 18 to be manufactured out of a composite, e.g., a screw according to Fig. 1 or an osteosynthesis plate according to Fig. 2, a predictable progression and predictable quantity and orientation of reinforcing elements in the form of fibers 6 or fibrous parts made out of a material with a higher X-ray absorption, are provided, tailored to the shape and application of the component 1 or 18. In addition, areas of varying fiber orientation or varying fiber progression can also

be provided relative to the longitudinally or transverse oriented alignment of the component 1 or 18.

Finally, at a total fiber percentage of 50 %v/v in a component 1 or 18, for example, the ratio of carbon atoms 6 to fibers 6 or fibrous parts made out of a material with a high X-ray absorption can be or has been altered, depending on the application requirement. It is also possible to distribute the total fiber percentage in the composite uniformly over the length and width of a component 1 or 18, but the ratio of carbon fibers 6 to fibers 6 or fibrous parts made out of a material with a high X-ray absorption changes as needed and depending on the application requirement. It is also possible to vary the stiffness of the connecting element by varying the orientation of used fibers from the force application point toward the free end. In another possible variant, the stiffness of the component is incrementally or continuously tapered by varying the orientation of the fibers viewed from the force application point to the free end.

Precisely in a component 18 designed as a strip or plate-shaped assembly piece, e.g., an osteosynthesis plate of the kind shown on Fig. 2, a concentration of fibers 6 is present in the area A of one or more recesses 14 or holes. If needed, it is here possible to reduce the percentage of fibers 6 or fibrous parts made out of a material with a higher X-ray absorption in these areas A. By contrast, if the percentage of fibers made out of a material with a higher X-ray absorption is also not reduced in the area of this concentration of fibers, even better contrasts can be achieved while targeting during the use of X-rays.

Subject: <u>COMPOSITE OF POLYMER OR CERAMIC MATERIALS AND COMPONENT MADE OF SUCH A COMPOSITE</u>

CLAIMS

1. Composite of polymer or ceramic material with a content of integrated reinforcing elements in the form of fibers or fibrous parts, for the manufacture of components exposed to tensile, bending, shear, compressive and/or torsional stress for use in implants, e.g., osteosynthesis plates, endoprostheses, screw coupling elements or in surgical instruments, characterized by the fact that polymer or ceramic material incorporates at least a small percentage of the content of reinforcing elements made out of a material whose X-ray absorption is higher than that of the material of the remaining reinforcing elements.

2. Composite according to claim 1, characterized by the fact that it consists of a polymer or ceramic material with a high fiber content, with the predominant use of continuous, long or short fibers.

3. Composite according to claim 1 or 2, characterized by the fact that it is prefabricated as a profiled rod material comprised of thermoplastics with carbon fibers and fibers made out of a material with a higher X-ray absorption, and can be or has been molded into a shape required for the final component (1, 18) in a thermoforming process.

4. Composite according to one of claims 1 to 3, characterized by the fact that it consists of carbon fiber-reinforced PAEK (poly-aryl-ether-ketone) and a percentage of fibers made out of a material with a higher X-ray absorption.

5. Composite according to one of claims 1 to 4, characterized by the fact that the carbon fibers and fibers made out of a material with higher X-ray absorption are designed as continuous fibers and/or fibers with a length exceeding 3 mm.

6. Composite according to claims 1 to 5, characterized by the fact that the used fibers (6) are enveloped on the surface by the matrix material both in the preform and the finished component (1, 18).

7. Composite according to claims 1 to 6, characterized by the fact that the fibers (6) or fibrous parts consist of a material with a higher X-ray absorption made out of a nonmagnetic material.

8. Composite according to claims 1 to 7, characterized by the fact that the fibers (6) or fibrous parts with a high X-ray absorption consist of tantalum, tungsten, gold or platinum, meaning a metal or metal oxides with high attenuation coefficients.

9. Component made out of a composite according to claims 1 to 8, characterized by the fact that a predictable progression and predictable quantity and orientation of reinforcing elements in the form of fibers (6) or fibrous parts made out of a material with a high X-ray absorption, are provided, tailored to the shape and application of the component (1, 18).

10. Component according to claim 9, characterized by the fact that areas of differing fiber orientation or fiber progression are provided relative to the longitudinally or transverse oriented alignment of the component (1, 18).

11. Component according to claims 9 and 10, characterized by the fact that the ratio of carbon fibers to fibers or fibrous parts made out of a material with a higher X-ray absorption can be or is variable at a total fiber percentage of approx. 50 %v/v, for example, depending on the application requirement.

12. Component according to claims 9 to 11, characterized by the fact that the total fiber percentage in the composite remains constant over their length or width, but this changes the ratio of carbon fibers

(6) to fibers (6) or fibrous parts made out of a material with a high X-ray absorption, depending on the application requirement.

13. Component in the form of a connecting element according to claims 9 to 12, characterized by the fact that the stiffness of the connecting element can be varied by varying the orientation of used fibers (6) from the force application point toward the free end.

14. Component in the form of a connecting element according to one of claims 9 to 13, characterized by the fact that the stiffness of the component (1) is incrementally or continuously tapered by varying the orientation of the fibers viewed from the force application point to the free end.

15. Component in the form of a strip or plate assembly part, e.g., an osteosynthesis plate, according to one of claims 9 to 14, characterized by the fact that a concentration of fibers (6) be present in the area (A) of one or more recesses (14) or holes in the component (18), wherein the percentage of fibers (6) or fibrous parts made out of a material with a high X-ray absorption is reduced in these areas, if necessary.

OIPE JC145 APR 2 4 2001 PATENT & TRADEMARK OFFICE

#4

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Please type a plus sign (+) inside this box → [+]

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	LUD-PT002(PA1083US)
First Named Inventor	Magerl et al.
COMPLETE IF KNOWN	
Application Number	09/701,104
Filing Date	22 November 2000
Group Art Unit	Not Yet Known
Examiner Name	Not Yet Known

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

COMPOSITE OF POLYMER OR CERAMIC MATERIALS AND COMPONENT MADE OF SUCH A COMPOSITE

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) May 26, 1999 as United States Application Number or PCT International Application Number PCT/EP99/03618 and was amended on (MM/DD/YYYY) ______ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1 56.

I hereby claim foreign priority benefits under 35 U.S.C 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
19823737.5	Germany	May 27, 1998	☐	☐	☒
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C 119(e) of any United States provisional application(s) listed below

Application Number(s)	Filing Date (MM/DD/YYYY)	
		☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
PCT/EP99/03618	May 26, 1999	

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☒ Customer Number 3624 → Place Customer Number Bar Code Label here
OR
☐ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Namely, the Attorneys of Volpe and Koenig, P.C.			

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☒ Customer Number or Bar Code Label 3624 OR ☐ Correspondence address below

Name					
Address					
Address					
City		State		ZIP	
Country		Telephone		Fax	

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
1-00 Fritz	MAGERL

Inventor's Signature	[signature]					Date	April 11, 2001
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CHX

☒ Additional inventors are being named on the 2 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 1 of 2

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 2 of 2

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor							
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Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor							
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6-00 Walter				SPIRIG				
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Post Office Address							
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